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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,537	09/09/2000	Adrienne W. Paton	19957-014500US	3288

20350 7590 01/31/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1633	7

DATE MAILED: 01/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/658,537	Applicant(s) PATON ET AL.	
	Examiner Brian Whiteman	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-116* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-116 are pending for examination in this instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-85, 88-107, and 110, drawn to a recombinant microorganism that displays on its surface a binding moiety that, when administered to an animal, competes with a ligand for binding to a receptor for the ligand, classifiable in class 424, subclass 93.4.

II. Claims 67, 86, 87, 88, 108-109, and 111, drawn to a purified chimeric carbohydrate; the pharmaceutical preparation as in claim 67, wherein the carbohydrate is lipopolysaccharide and the carbohydrates is delivered as an intact or partially intact membrane preparation selected from the group consisting of bacterial ghosts, liposomes, or membrane vesicles, classifiable in class 514, subclass 23.

III. Claims 112-116, drawn to a method of testing for the presence of a toxin or a pathogenic microorganism in a sample, classifiable in class 435, subclass 7.2.

Claim 67 link(s) inventions I and II. Claim 88 links inventions I and II. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 67 or 88. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or

including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention I is directed to a recombinant microorganism and invention II is directed to a chimeric carbohydrate. Inventions I and II can be used in distinct methods of reducing a toxin in a host and invention I has a different mode of operation, different function and different effect than invention II. It would be an undue burden on the examiner because the search for invention I would not overlap with the search for invention II. Thus, invention I and II are distinct.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I and III constitute patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, none of the method steps cited

in invention III recites a similar method of using the recombinant microorganism generated from Group I. Each of the inventions I-III comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another.

If applicant elects group I, applicant is further required to elect a species because claims 1 and 2 are generic to a plurality of disclosed patentably distinct species comprising bacteria, fungi, Mycoplasma, and yeast. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1, 7, 8, 9, 10, 11, 12, 13, 14, and 15 are generic to a plurality of disclosed patentably distinct species comprising a toxin selected from enterotoxin, shiga, clostridial, and cholera. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is required to elect species that corresponds to the elected invention or another restriction will be required. For example if applicants elect Group I and elect shiga toxin in claim 9, then claims not directed to shiga toxin will be considered non-elected.

Claims 67, 69, 70, 71, and 72 are generic to a plurality of disclosed patentably distinct species comprising a toxin selected from enterotoxin, shiga, clostridial, and cholera. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1, 25, 26, 28, 29, 30, 31, 33, 34, 35, and 37 are generic to a plurality of disclosed patentably distinct species comprising a binding moiety selected from a terminal sialic acid, terminal mannose residue, terminal fucose residue, galactose residue, a 3'-sialoside, a 6'-

sialoside, sialyl Lewis^{x}, a sialyl Lewis^{a}, or an oligosaccharide selected from the group consisting of see page 73, lines 3-21. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1, 60, 61, 62, and 63 are generic to a plurality of disclosed patentably distinct species comprising 1) a microorganism is selected from having a reduced production of external masking polysaccharide molecules, 2) the microorganism is selected to provide some resistance to antimicrobial activity of microflora potentially resident in the gut or 3) the microorganism is resistant to the major families of colicins. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1, 25, 26, and 27 are generic to a plurality of disclosed patentably distinct species comprising a pathogenic organism selected from the group consisting of staphylococcus pneumonia, H.influenza, H. parainfluenza, Chlamydia trachomatis, Acanthamoeba, and Pseudomonias spp. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 67, 73, 88, and 94 are generic to a plurality of disclosed patentably distinct species comprising a receptor mimic comprises an oligosaccharide selected from the group consisting of (see page 73, claim 37; page 78, claim 73; page 81-82, claim 94). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1 and 45 are generic to a plurality of disclosed patentably distinct species comprising a toxin selected from a group consisting of Escherichia, Salmonella, Shigella, Citrobacter, Helicobacter, Yersinia, Vibrio, Aeromonas, Campylobacter, Pseudomonas,

Pasteurella, Neisseria, Haemophilus, Klebsiella, Staphylococcus, Streptococcus, Clostridium, rotavirus, and Entamoeba. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1, 46, and 47 are generic to a plurality of disclosed patentably distinct species comprising a nucleotide sugar selected from GDP-Man, UDP-Glc, UDP-Gal, UDP-0GlcNAc, UDP-GalNAc, CMP-sialic acid, GDP-Fuc, and UDP-xylose. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1, 58, 67, 82, 78, and 83 are generic to a plurality of disclosed patentably distinct species comprising a microorganism is selected from a genus selected from the group consisting of Escherichia, Salmonella, Acidophilus, Lactobacillus, Lactococcus, and Bifidobacterium. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group II, claims 67 and 86, are generic to a plurality of disclosed patentably distinct species comprising a sugar moiety selected from the group consisting of bacterial ghosts, liposomes incorporating chimeric lipopolysaccharide, or membrane vesicles. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants elect group III, claims 112, 115, and 116 are generic to a plurality of disclosed patentably distinct species comprising a sugar moiety selected from the group consisting of (see pages 84-85, claims 115-116). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the literature search required for Group 1 is not required for Group II and III, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner 1633
10/5/01

DAVE T. NGUYEN
PRIMARY EXAMINER